MAY 1 2013

510(k) Summary of Safety and Effectiveness

Submitted by:	United Orthopedic Corporation
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Date of Summary:	November 15, 2012
Contact Person:	Fang-Yuan Ho
	Manager, Regulatory Affairs
Proprietary Name:	UTF Stem, reduced
Common Name:	Hip Stem
Device Classification Name and Reference:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis under 21CFR 888.3358
Device Class	Class II
Panel Code	Orthopaedics Device
Device Product Code	LPH, KWY, LZO
Predicate Device:	"UNITED" UTF Stem (K110245)

Device Description:

This subject device is a modification and an additional size extension to the previously cleared "UNITED" UTF Stem (K110245). The materials, safety and effectiveness of this subject device are identical to "UNITED" UTF Stem (K110245). Compared with the UTF Stem (K110245), the distal width of UTF Stem–reduced is reduced to provide more selection for clinical demand, and the thread diameter of impact hole of UTF Stem-reduced is enlarged to increase the mechanical strength of stem holder which is locked with impact hole.

As the same as UTF Stem (K110245), UTF Stem–reduced, forged from a Ti-6Al-4V alloy (ASTM F136), is a modular, wedge-shaped stem with 12/14 neck taper and 130° neck angle. The proximal part of each femoral stem is plasma coated with CP Ti powder (ASTM F1580) in thickness 500±127μm. UTF Stem–reduced is available with standard and high offset options, and each type is available in sizes #1~11. The specifications of UTF Stem–reduced in size #1~6 and #9 are identical with UTF Stem (K110245) in size #7.5, 9, 10, 11, 12, 13, 16.5, respectively, while size #7, 8, 10 and 11 are new items which is between size # 13 and #22 in UTF Stem (K110245). These modifications will not affect its safety and effectiveness.

For total hip replacement, UTF Stem–reduced can be used in conjunction with UNITED Femoral Head (K994078, K022520, K111546 and K122504), Ceramic Femoral Head (K103497, K112463), U2 Acetabular Cup Liner (K050262), XPE Cup Liner (K111546), U2 HA/Ti Plasma Spray Cup (K050262, K121777), U2 Ti Plasma Spray Cup (K050262, K121777) and U2 Ti Porous Coated Cup (K111546). As using with U2 Acetabular Cup Liner (K050262), UTF Stem–reduced can be used with 26 mm and 28 mm metal Femoral Head (K994078, K022520, K122504) and 28 mm Ceramic Femoral Head (K103497). As using with XPE Cup Liner (K111546), UTF Stem can be used with 28 mm, 32 mm and 36 mm metal Femoral Head (K022520, K111546, K122504) and 28 mm, 32 mm and 36 mm Ceramic Femoral Head (K103497, K112463).

For bipolar hip replacement, UTF Stem–reduced also can be used in conjunction with 26 mm, 28 mm, 32mm and 36mm metal Femoral Head (K994078, K022520, K111546, K122504), 28 mm, 32 mm and 36 mm Ceramic Femoral Head (K103497, K112463) and Bipolar implants (K101670). UNITED Femoral Head and Bipolar Cap are made of Co-Cr-Mo alloy, while Ceramic Femoral Head is manufactured from alumina. Acetabular Cup Liner and Bipolar Cap Liner are made of UHMWPE, while U2 Acetabular Cup shells are manufactured from forged Titanium alloy.

Indications:

This device is indicated for use in total hip replacement or bipolar hip replacement undergoing primary and revision surgery for the following conditions: non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia; inflammatory degenerative joint disease such as rheumatoid arthritis; correction of functional deformity; treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; revision procedures where other treatments or devices have failed.

This device is designed for cementless use.

Basis for Substantial Equivalence:

The subject device is a modification and an additional size extension to the previously cleared "UNITED" UTF Stem (K110245). The safety and effectiveness of the subject device are substantially equivalent to the previously cleared "UNITED" UTF Stem (K110245), except for the reduced distal profile and increased the thread diameter of the impact hole. The modifications do not change the intended use or fundamental scientific technology.

Non-Clinical Testing:

The stem fatigue test and neck fatigue test for worst-case in UTF stem (K110245) have been completed according to ISO 7206-4 and ISO 7206-6, respectively. No additional non-clinical testing was performed for UTF Stem–reduced because the enlarged thread diameter of impact hole and reduced distal width did not decrease the stem fatigue strength and neck fatigue strength based on the FEM analysis.

The chemical analysis, microstructural characterization and mechanical strength of the modified coating have also evaluated. The results conform to the requirements of FDA Guidance, "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements".

Based upon engineering analysis of the design modification, UTF Stem–reduced is substantially equivalent to devices currently marketed. Therefore, the device is as safe, as effective, and performs at least as safely and effectively as legally market predicates.

Clinical Testing:

Clinical testing was not required for this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

United Orthopedic Corporation
% Ms. Fang-Yuan Ho
Regulatory Affairs, Manager
No. 57, Park Ave 2, Science Park
Hsinchu, Taiwan 300

Letter dated: May 1, 2013

Re: K123550
Trade/Device Name: UTF Stem, reduced
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, KWY, LZO
Dated: April 3, 2013
Received: April 4, 2013

Dear Ms. Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510 (k) Number (if known): K123550

Device Name: UTF Stem, reduced

Indications for Use:

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This device is designed for cementless use.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices